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Obgemsa (*vibegron*)

An overview of Obgemsa and why it is authorised in the EU

What is Obgemsa and what is it used for?

Obgemsa is a medicine used to treat adults with overactive bladder syndrome (OAB). It is used to treat symptoms of the condition such as urgency (sudden urge to urinate), increased urinary frequency (need to urinate frequently) and urge incontinence (involuntary leakage when a sudden strong need to urinate is felt).

Obgemsa contains the active substance vibegron.

How is Obgemsa used?

The medicine can only be obtained with a prescription. It is available as tablets to be taken by mouth once a day. For more information about using Obgemsa, see the package leaflet or contact your doctor or pharmacist.

How does Obgemsa work?

The active substance in Obgemsa, vibegron, attaches to a receptor (target) found in the muscle cells of the bladder. By attaching to and activating this receptor, vibegron relaxes the bladder muscles and changes the way the bladder contracts, preventing unwanted or involuntary urination.

What benefits of Obgemsa have been shown in studies?

Obgemsa was investigated in a main study involving over 1,500 adults with OAB. The study compared Obgemsa with placebo (a dummy treatment) and tolterodine (another medicine used for OAB) and looked at the change in how often patients needed to urinate in a 24-hour period after 12 weeks of treatment. It also looked at the number of urge incontinence episodes in a 24-hour period in a subgroup of patients who experienced one or more episodes of urge incontinence every day.

The study showed that Obgemsa was more effective than placebo and as effective as tolterodine in reducing how often patients urinated in a 24-hour period. Before treatment, patients needed to urinate between 11 and 12 times per day; after 12 weeks, this was 9.3 times in patients given Obgemsa (a decrease of 1.8, on average), compared with 10 times in patients given placebo (a decrease of 1.3, on average). The decrease seen in patients taking tolterodine was 1.6, on average. The group of patients

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with urge incontinence experienced about 3.5 incontinence episodes per day before treatment; after 12 weeks of treatment, the number of incontinence episodes decreased by 2.0 in patients given Obgemsa, compared with 1.4 in those given placebo and 1.8 in those given tolterodine.
The beneficial effects of Obgemsa did not decrease over time and were still seen after 52 weeks of treatment.

What are the risks associated with Obgemsa?

For the full list of side effects and restrictions with Obgemsa, see the package leaflet. The most common side effects with Obgemsa (which may affect up to 1 in 10 people) include urinary tract infection (infection of structures that carry urine), headache, diarrhoea and nausea (feeling sick).

Why is Obgemsa authorised in the EU?

The European Medicines Agency considered that the benefits of Obgemsa, although modest, are relevant for patients with OAB, and safety data raised no concerns. The Agency therefore decided that Obgemsa's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Obgemsa?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Obgemsa have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Obgemsa are continuously monitored. Suspected side effects reported with Obgemsa are carefully evaluated and any necessary action taken to protect patients.

Other information about Obgemsa

Obgemsa received a marketing authorisation valid throughout the EU on 27 June 2024.

Further information on Obgemsa can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/obgemsa.

This overview was last updated in 07-2024.